

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF VIRGINIA  
NORFOLK DIVISION**

BASF PLANT SCIENCE, LP,

Plaintiff,

v.

COMMONWEALTH SCIENTIFIC AND  
INDUSTRIAL RESEARCH  
ORGANISATION,

Defendant.

Civil Action No. 2:17cv503-HCM-LRL

Patent Case

COMMONWEALTH SCIENTIFIC AND  
INDUSTRIAL RESEARCH  
ORGANISATION, GRAINS RESEARCH  
AND DEVELOPMENT CORP., AND  
NUSEED PTY LTD.,

Plaintiffs-Counterclaimants,

v.

BASF PLANT SCIENCE, LP, AND  
CARGILL, INCORPORATED,

Defendants-  
Counterdefendants,

BASF PLANT SCIENCE GMBH,

Counter-Counterclaimant.

**BASF PLANT SCIENCE, LP'S AND BASF PLANT SCIENCE GMBH'S  
OPENING CLAIM CONSTRUCTION BRIEF**

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**I. PRELIMINARY STATEMENT**

BASF Plant Science, LP and BASF Plant Science GmbH (together, “BASF”) hereby submit their Opening Claim Construction Brief. BASF respectfully submits that the Court should construe the disputed terms according to BASF’s proposed constructions, which are consistent with the plain language of the claims, the specifications and prosecution histories. In contrast, Commonwealth Scientific and Industrial Research Organisation, Grains Research and Development Corp. and Nuseed Pty Ltd. (collectively, “CSIRO”) proposes constructions that are wholly divorced from the intrinsic evidence.

In a transparent attempt to salvage the validity of its claims, CSIRO’s proposed claim constructions ignore the plain and ordinary meaning of simple, straightforward terms. For example, CSIRO argues that “at least [X] %” and “[X] %” are restricted by some nebulous “upper limit enabled by the specification,” and “less than [X] %” is restricted by an equally nebulous “lower limit enabled by the specification.” Those constructions – based on whatever limit would allow the claims to be enabled – reflect an improper attempt to construe claim terms to preserve validity.

The same is true for the term “seed-preferred promoter.” To avoid a determination of indefiniteness, CSIRO argues that the term is non-limiting – despite the fact that the specification and prosecution history repeatedly emphasize that the degree of promoter activity in a seed is an integral part of the alleged invention. CSIRO’s litigation-driven position is underscored by its alternative construction that “seed-preferred promoter” actually means “seed-specific promoter” – the exact term that the patentee attempted to distinguish “seed-preferred promoter” from during prosecution.

Other CSIRO constructions ignore the plain meaning of simple, straightforward terms in a blatant attempt to impermissibly broaden the claims to cover accused products that are outside

their scope. For example, CSIRO argues that “SEQ ID NO:[X]” extends to both the specified DNA sequence, and also an undefined, “equivalent sequence.” But CSIRO recited broadening language (“at least [X]% identical to”) in its claims when capturing sequences broader than an exact sequence; in contrast, the term “SEQ ID NO:[X]” – without such broadening language – is restricted to the exact sequence. And during prosecution, the patentee expressly disavowed any sequence homologs or analogs. CSIRO likewise seeks to improperly broaden the scope of the terms “catalyses [desaturation/elongation]” and “a desaturase [an exogenous desaturase] which desaturates,” by reading in the term “capable of.” CSIRO also attempts to broaden the term “capable of directing expression,” by reading out the term “expression” and expanding “directing” to “stimulating or modulating the transcription of the coding sequence in an appropriate cell.” Finally, CSIRO inexplicably drops the word “canola” from the term “the extracted canola oil,” in an attempt to broaden that term.

## **II. BACKGROUND**

There are 17 patents at issue in this proceeding, which are generally directed to synthesis of long-chain polyunsaturated fatty acids (“LC-PUFAs”) in genetically modified plants.<sup>1</sup>

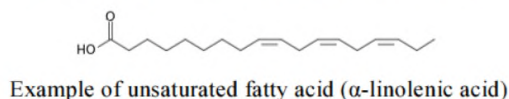
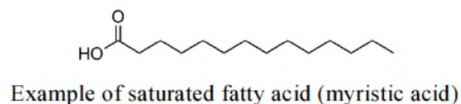
### **A. Fatty Acid Nomenclature**

Fatty acids are carbon chains that terminate with a carboxylic group (-COOH). Fatty acids are classified by the length of the carbon chain (*e.g.*, C20 has 20 carbons) and the number and position of double bonds between carbons, using the syntax of carbons:double-bonds<sup>double-bond positions</sup>. For example, a C20 fatty acid with 5 double-bonds at the 5th, 8th, 11th, 14th and

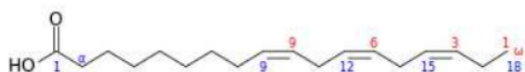
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<sup>1</sup> U.S. Patent Nos. 7,642,346 (“the ’346 Patent”); 7,807,849 (“the ’849 Patent”); 7,834,250 (“the ’250 Patent”); 8,106,226 (“the ’226 Patent”); 8,288,572 (“the ’572 Patent”); 8,575,377 (“the ’377 Patent”); 8,853,432 (“the ’432 Patent”); 9,458,410 (“the ’410 Patent”); 9,926,579 (“the ’579 Patent”); 9,932,541 (“the ’541 Patent”); 9,951,357 (“the ’357 Patent”); 9,963,723 (“the ’723 Patent”); 9,969,954 (“the ’954 Patent”); 9,970,033 (“the ’033 Patent”); 9,994,792 (“the ’792 Patent”); 9,994,880 (“the ’880 Patent”); 10,125,084 (“the ’084 Patent”).

17th carbons is labeled as 20:5<sup>Δ5,8,11,14,17</sup>. Polyunsaturated fatty acids (such as LC-PUFAs) have two or more double bonds, while monounsaturated fatty acids have one double bond, and saturated fatty acids have no double bonds.



Fatty acids are further classified according to the distance of the farthest double-bond from the end of the carbon chain; an “ω3” (“omega 3”) fatty acid, such as 20:5<sup>Δ5,8,11,14,17</sup>, has its farthest double bond (at C17) a distance of 3 carbons from the end of the chain (C20). An example of this numbering scheme is shown below (numbers in blue identify the carbon position, while numbers in red identify the distance from the omega end of the chain).



Finally, certain fatty acids have unique names; *e.g.*, 20:5<sup>Δ5,8,11,14,17</sup> is known as “eicosapentaenoic acid” or “EPA.”

## **B. LC-PUFA Synthesis Generally**

As the patentee acknowledged in the patents-in-suit, it was known that LC-PUFAs are synthesized from precursor fatty acids (LA and ALA).

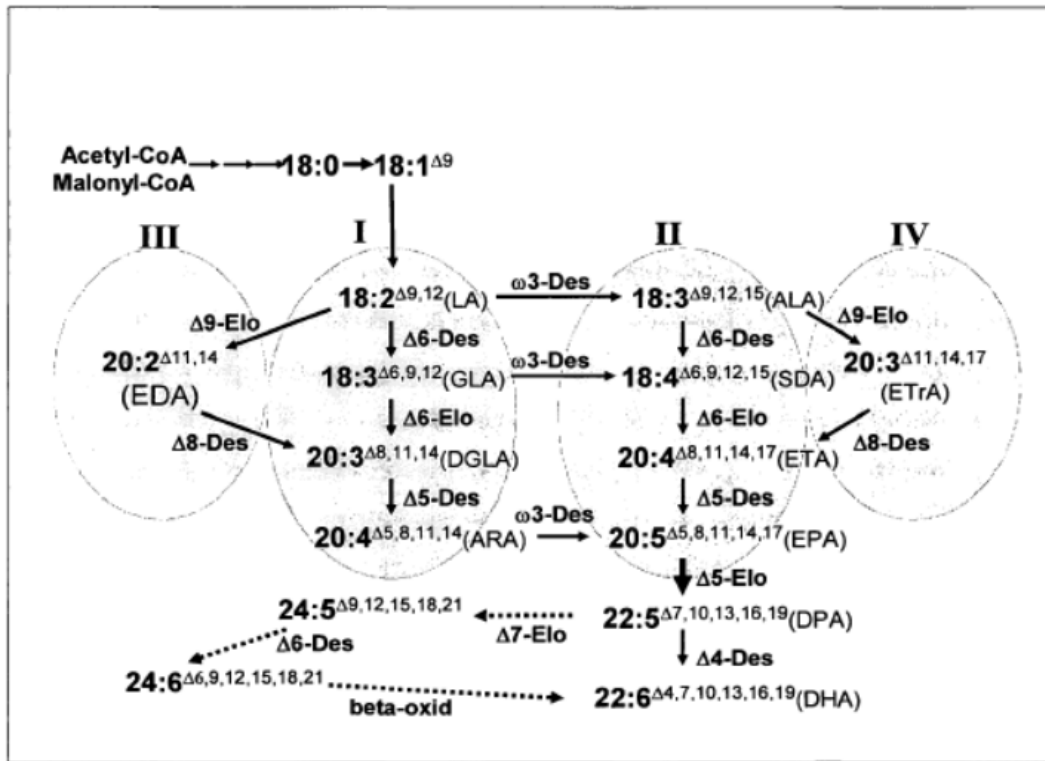


Figure 1

'849 Patent (D.I. 58-4), Fig. 1. Desaturases (abbreviated as "Des" in the diagram) are enzymes that add a double bond to, *i.e.*, desaturate, a fatty acid. *Id.* at col.2 ll.17-19. Similarly, elongases (abbreviated as "Elo" in the diagram) are enzymes that add 2 carbon atoms to, *i.e.*, elongate, the fatty acid. *Id.* at col.2 ll.19-20. Desaturases are classified by the carbon in the fatty acid that is targeted by the particular enzyme; *e.g.*, a  $\Delta^4$  desaturase adds a double bond at the C4 position. *See, e.g., id.* at Fig. 1. Elongases are classified by double bond positioning in the fatty acid that is targeted by the enzyme; *e.g.*, a  $\Delta^6$  elongase adds two carbons to a fatty acid that contains a double bond at the C6 position. *See, e.g., id.* Thus, Figure 1 of the '849 Patent depicts "a series of alternating . . . desaturations and elongation reactions" that convert certain fatty acids (*e.g.*, EPA) to other fatty acids (*e.g.*, DPA). *See, e.g. id.* at col.2 ll.15-17.



### C. Expression of Genes in Transgenic Plants

Although plants can synthesize precursor LC-PUFAs, ALA and LA, they cannot synthesize other LC-PUFAs that are desirable for human health, *e.g.*, EPA and DHA. Synthesis of such desirable LC-PUFAs involves genetically modifying plants by inserting genes from the pathways depicted in Figure 1, *supra*, that are missing in plants. Before the patents-in-suit, it was known how to express such inserted genes in genetically modified plants in order to synthesize LC-PUFAs. *See* '849 Patent (D.I. 58-4), col.3 l.63-col.4 l.37. One of the elements that regulates expression of a gene in the various tissues of the plant is a gene's promoter; it indicates where an early stage of gene expression will be initiated. *See id.* at col.40 l.35-col.41 l.25.

### III. LEGAL STANDARD

The meaning of a patent and the terms of art within its claims are questions of law exclusively for the Court. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996). The claims of the patent define the invention to which the patentee has rights. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (*en banc*). "In construing claims, this court relies primarily on the claim language, the specification, and the prosecution history." *Vedderi, LLC v. Google, Inc.*, 744 F.3d 1376, 1382 (Fed. Cir. 2014).

Claim construction begins with the language of the claims. *Abbott Labs. v. Andrx Pharm., Inc.*, 452 F.3d 1331, 1336 (Fed. Cir. 2006). Claim terms "are generally given their ordinary and customary meaning," as it would have been understood by a person of ordinary skill in the art. *Phillips*, 415 F.3d at 1312–13. When the plain and ordinary meaning of a claim term is "readily apparent even to lay judges," then claim construction "involves little more than the application of the widely accepted meaning of commonly understood words." *Id.* at 1314.

Where claim terms are ambiguous or disputed, then [construction] turn[s] to the specification” which is “always highly relevant to the claim construction analysis.” *Abbott Labs.*, 452 F.3d at 1336. In only two instances do the Courts deviate from the plain and ordinary meaning of a claim: “1) when a patentee sets out a definition and acts as his own lexicographer, or 2) when the patentee disavows the full scope of the claim term[.]” *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1371 (Fed. Cir. 2014). Disavowal requires that the specification or prosecution history clearly indicate that the invention is limited to a particular form or does not include a particular feature. *Id.*

Only if the intrinsic record is ambiguous may a court seek guidance from extrinsic evidence, “which ‘consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.’ ” *Power Integrations, Inc. v. Fairchild Semiconductor Int’l, Inc.*, 711 F.3d 1348, 1360 (Fed. Cir. 2013). Extrinsic evidence may not be used ‘to contradict claim meaning that is unambiguous in light of the intrinsic evidence.’ ” *Summit 6, LLC v. Samsung Elecs. Co.*, 802 F.3d 1283, 1290 (Fed. Cir. 2015) (citing to *Phillips*, 415 F.3d at 1324); *Vederi*, 744 F.3d at 1382 (“extrinsic evidence may be less reliable than the intrinsic evidence”).

#### IV. ARGUMENT

##### A. **The term “at least [X]” should be construed as open-ended, without an upper limit, consistent with its plain and ordinary meaning.**

The term “at least [X]” appears in every independent claim of 7 asserted patents (the ’849, ’226, ’572, ’377, ’432, ’410, and ’723 Patents), except for claims 18 and 20 of the ’723 Patent. The term specifies a range for the (1) percentage of a particular fatty acid(s) produced in

a claimed seed; and/or (2) conversion ratio (a/k/a efficiency of conversion) between particular fatty acids.<sup>2</sup> BASF's and CSIRO's respective constructions are set forth in the table below.

<u>Term</u>	<u>BASF's Proposed Construction</u>	<u>CSIRO's Proposed Construction</u>
"at least [X]%"	Plain and ordinary meaning	"greater than or equal to X%, and less than the inherent upper limit enabled by the specification"

The term "at least [X]%" has a plain and ordinary meaning. *See, e.g., Quantum Corp. v. Rodime, PLC*, 65 F.3d 1577, 1581 (Fed. Cir. 1995) (the term "at least" means "as the minimum," and " 'at least 600 tpi' . . . expressly represents an open-ended range, i.e. 600 tpi and up' "); *Lantech, Inc. v. Keip Mach. Co.*, 32 F.3d 542, 546 (Fed. Cir. 1994) ("[T]he term 'at least two' sets forth the minimum number of a particular element required."). That term sets a minimum in relation to an open-ended range. But, CSIRO proposes associating the term with a ceiling: "less than the inherent upper limit enabled by the specification." There is no basis in the claims, the specification or the prosecution history for such a construction. CSIRO's contrived construction is nothing more than an attempt to salvage overly-broad claims, which lack written description support and are not enabled. As the Federal Circuit has held – in the specific context of the same "at least [X]%" term – "a patentee chooses broad claim language at the peril of losing any claim

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<sup>2</sup> The term "at least [X]%" appears in many claims ('849 Patent, claims 1, 3-6, 10, 11; '226 Patent, claims 1, 3-18; '572 Patent, claims 1, 3-18; '377 Patent, claims 1, 3-18; '432 Patent, claims 1, 3-18, 26-40; '410 Patent, claims 1-15; '723 Patent, claims 1, 2, 6-10, 16; '579 Patent, claims 1, 7; '357 Patent, claims 28-30, 39-41, 43-45; '792 Patent, claims 1, 5; '541 Patent, claims 1, 7, 8, 15, 20, 21; '954 Patent, claims 7, 8, 20, 21; '084 Patent, claims 1, 9), including in other contexts. Mindful of the Court's resources, and given the sheer number of claims that recite the term "at least [X]%", BASF focuses here on the contexts relevant to the parties' dispute.

that cannot be enabled across its full scope of coverage.”<sup>3</sup> *MagSil Corp. v. Hitachi Global Storage Techs., Inc.*, 687 F.3d 1377, 1381 (Fed. Cir. 2012).

Claim 1 of the '226 Patent is representative of the independent claims at issue:

1. A process for producing oil containing eicosapentaenoic acid [*i.e.*, EPA] and docosapentaenoic acid [*i.e.*, DPA], comprising the steps of obtaining a transgenic *Brassica* or *Arabidopsis* plant seed comprising eicosapentaenoic acid and docosapentaenoic acid, wherein the total fatty acid of the transgenic seed comprises **at least 2.5% ω3 C20 fatty acids** (w/w) and wherein the docosapentaenoic acid is present at a level based on **a conversion ratio of eicosapentaenoic acid to docosapentaenoic acid of at least 5%** (w/w), and extracting oil from the transgenic *Brassica* or *Arabidopsis* plant seed so as to thereby produce the oil.

'226 Patent (D.I. 59-1), claim 1 (emphasis added). The plain language of the claim does not set an upper limit for the percentage of ω3 C20 fatty acids (in red) or the conversion ratio of EPA to DPA (in blue). Nor do the dependent claims of the '226 Patent (and the other 6 patents at issue) set an upper limit. There can be no question that the patent drafter specifically intended the plain and ordinary, open-ended meaning of “at least [X]%.”

There is likewise no support in the specification for imposing a ceiling on the “at least [X]%” range. Indeed, the specification of the '226 Patent uses the term “at least” more than 350 times (frequently in the same context as the claims), without specifying an upper limit as a cap on the range. For example, in the section of the specification entitled “Levels of LC-PUFA Produced,” the specification discloses the ranges of fatty acid percentages (including the C20 ω3 fatty acids of the claims at issue) in various embodiments; the term “at least” prefaces all of the ranges, and without any upper limit:

In certain embodiments, where the recombinant cell is useful in a fermentation process such as, for example, a yeast cell, the level of EPA that is produced may be **at least 0.21%** of the total fatty acid in the cell, preferably **at least 0.82%** or

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<sup>3</sup> By including a nebulous “inherent upper limit enabled by the specification,” CSIRO’s proposed definition only makes the term *less* clear. No specific upper limit is proposed. That provides an independent basis to reject CSIRO’s proposed construction.

**at least 2%** and even more preferably **at least 5%**.

In other embodiments, the total fatty acid of the recombinant cell may comprise **at least 1.5%** EPA, preferably **at least 2.1%** EPA, and more preferably **at least 2.5%**, **at least 3.1%**, **at least 4%** or **at least 5.1%** EPA.

In further embodiments, where the recombinant cell is useful in a fermentation process or is a plant cell and DPA is produced, the total fatty acid in the cell may comprise **at least 0.1%** DPA, preferably **at least 0.13%** or **at least 0.15%** and more preferably **at least 0.5%** or **at least 1%** DPA.

In further embodiments, the total fatty acid of the cell may comprise **at least 2%** C20 LC-PUFA, preferably **at least 3%** or **at least 4%** C20 LC-PUFA, more preferably **at least 4.7%** or **at least 7.9%** C20 LC-PUFA and most preferably **at least 10.2%** C20 LC-PUFA.

In further embodiments, the total fatty acid of the cell may comprise **at least 2.5%** C20  $\omega$ 3 LC-PUFA, preferably **at least 4.1%** or more preferably **at least 5%** C20  $\omega$ 3 LC-PUFA.

In other embodiments, where both EPA and DPA are synthesized in a cell, the level of EPA reached is **at least 1.5%**, **at least 2.1%** or **at least 2.5%** and the level of DPA **at least 0.13%**, **at least 0.5%** or **at least 1.0%**.

'226 Patent (D.I. 59-1), col.28 ll.37-62 (emphasis added). The same is true for that section's disclosure of the conversion ratio of various embodiments:

In a preferred embodiment, the conversion efficiency is for ALA to EPA. In particular embodiments, the conversion ratio for production of EPA in a recombinant cell may be **at least 0.5%**, **at least 1%**, or **at least 2%**. In another embodiment, the conversion efficiency for ALA to EPA is **at least 14.6%**. In further embodiments, the conversion ratio for production of DPA from EPA in a recombinant cell is **at least 5%**, **at least 7%**, or **at least 10%**. . . . In a particular embodiment, the conversion efficiency of ALA to  $\omega$ 3 products through a  $\Delta$ 6 desaturation step and/or an  $\Delta$ 9 elongation step in a recombinant cell, preferably a plant cell, more preferably a seed cell, is **at least 22%** or **at least 24%**. Stated otherwise, in this embodiment the ratio of products derived from ALA to ALA (products:ALA) in the cell is **at least 1:3.6**.

*Id.* at col.29 ll.10-29 (emphasis added). Contrary to CSIRO's position, the intrinsic evidence is unambiguous that "at least [X]%" is an open-ended range.<sup>4</sup>

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<sup>4</sup> There is no disavowal of scope in the prosecution history with respect to this term.

District courts have consistently rejected virtually identical attempts to restrict the broad “at least” language of a claim. For example, the Southern District of California did not impose an upper limit with respect to a claim limitation requiring that “the specific signal is **at least 3 fold greater than** the same antibody conjugated to Pacific Blue.” *Regents of the Univ. of California v. Affymetrix, Inc.*, No. 17-CV-01394-H-NLS, 2018 WL 4216361, at \*9-10 (S.D. Cal. Sept. 4, 2018) (emphasis added). Similar to CSIRO’s argument here, the Plaintiffs in *Regents* argued that there is “an inherent upper limit in the range of about 20-25 fold.” *Id.* at \*9. The court’s analysis is instructive. The court found that “[t]he claim language places no express upper limit on the increase in signal.” *Id.* at \*10. And so here. The court further explained that it was unaware of any legal authority supporting the imposition of an upper limit:

Plaintiffs have failed to provide the Court with any authority . . . that the inherent upper limit of an open-ended claim term must be limited to what was known in the art at the time of the invention and would not include changes to that upper limit in the future. . . . In the absence of such authority, the Court declines to adopt Plaintiffs’ proposed inherent upper limit of about 20-25.

*Id.* (emphasis added).

The District of Delaware also refused to impose an upper limit. *See Spectrum Pharm., Inc. v. InnoPharma, Inc.*, No. CV 12-260-RGA-CJB, 2014 WL 3365684 (D. Del. July 3, 2014), report and recommendation adopted, No. CV 12-260-RGA-CJB, 2014 WL 4247182 (D. Del. Aug. 26, 2014). In *Spectrum*, there were a variety of claim terms with open-ended ranges, *e.g.*, “consists of **at least 92%** by weight of the (6S) diastereoisomer.” *Id.* at \*4 (emphasis added). And yet, Defendants argued that the upper limit was 98%. *Id.* at \*5. In rejecting that argument, the *Spectrum* court began with the plain language of the claims. The court stressed that the Federal Circuit has found the ordinary meaning of the term “at least” to be “an ‘open-ended range’ starting at . . . the numerical value in the claim.” *Id.* at \*4. Just as here, “the claim language does not provide reason to impose an upper limit . . . and indeed suggests that no such

upper limit was contemplated.” *Id.* Also similarly, “[t]he specification does not explicitly or implicitly suggest that any upper limit . . . would result . . . .” *Id.* at \*5. Notably, the court rejected Defendants’ argument that the claims must be construed to avoid invalidity. *Id.* at \*8-9. The fact that the claims here are invalid for lack of written description and nonenablement likewise does not warrant importing a limitation into the claims.

The District of Arizona is yet another example of a district court refusing to impose an upper limit on the term “at least.” *See Rowpar Pharm. Inc. v. Lornamead Inc.*, No. CV-13-01071-PHX-DGC, 2014 WL 1259777, at \*11 (D. Ariz. Mar. 25, 2014). There, the term at issue was “**at least 0.1%** chlorine dioxide.” *Id.* (emphasis added). Lornamead asserted “that it should be construed to mean that ‘chlorine dioxide is present in a concentration from 0.1% to no more than 2.0%.’” *Id.* As with other courts, the *Rowpar* court stressed that the Federal Circuit has found the ordinary meaning of the term “at least” to simply be “a range with a defined lower limit,” and held:

the ordinary meaning of ‘at least’ sets a lower limit on the claimed range but says nothing about the upper limit, and Lornamead has not presented intrinsic evidence that the patentee intended the claims using ‘at least’ to have an upper bound.

*Id.*

CSIRO may attempt to rely on *Andersen Corp. v. Fiber Composites, LLC*, 474 F.3d 1361, 1376-77 (Fed. Cir. 2007) to support its proposed construction. *Andersen* is not relevant to the present **claim construction** dispute. *Andersen* did not address construction of open-ended claim terms, and it did not stand for the proposition that plainly open-ended claim language should be construed to be capped with an upper limit. Rather, the question on appeal was whether Fiber satisfied “the heavy burden required to overturn the jury’s verdict[]” that the particular open-

ended claims at issue were enabled.<sup>5</sup> The Federal Circuit held that Fiber had not met its burden.<sup>6</sup>

There is a second independent reason that *Andersen* is irrelevant. There, the Federal Circuit addressed whether a claim term had an “inherent upper limit” (*i.e.*, the maximum that could be theoretically achieved), not an “inherent upper limit **enabled by the specification**,” as CSIRO proposes here. CSIRO vaguely proposes as the upper limit an undefined number that this Court finds appropriate to salvage the asserted, invalid claims. The Federal Circuit has unequivocally held that such a construction would be improper. *Chef Am., Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1374 (Fed. Cir. 2004) (“This court, however, repeatedly and consistently has recognized that courts may not redraft claims, whether to make them operable or to sustain their validity.”).

For all of the above reasons, BASF respectfully submits that the Court should construe the term “at least [X]” as an open-ended term, without an upper limit, consistent with its plain and ordinary meaning.

**B. The term “less than [X]” should be construed as open-ended, without a lower limit, consistent with its plain and ordinary meaning.**

The term “less than [X]” specifies a range for the percentage of a particular fatty acid(s) produced in a claimed seed. BASF’s and CSIRO’s respective constructions mirror their respective constructions of the term “at least [X]” above, and are set forth in the table below.

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<sup>5</sup> The claims at issue in *Andersen* recited a mixture of polymer and wood fiber with “a Young’s modulus rating of greater than [X].” *Id.* at 1376. Testimony at trial established that a person of skill in the art would have known that the Young’s modulus of the mixture had to be between the value for the polymer and the value for wood fiber. *Id.* at 1377. The Federal Circuit explained that a jury was free to find the particular open-ended claims at issue **enabled** because “there is an inherent, albeit not precisely known, upper limit and the specification enables one of skill in the art to approach that limit.” *Id.*

<sup>6</sup> The *Regents* Plaintiffs likewise relied on *Andersen* for the proposition that open-ended claims should be capped with an “inherent upper limit.” 2018 WL 4216361, at \*10. But, as discussed above, the *Regents* court rejected that argument, given the dearth of authority supporting such a construction. *Id.*



<u>Term</u>	<u>BASF's Proposed Construction</u>	<u>CSIRO's Proposed Construction</u>
"less than [X]%" <sup>7</sup>	Plain and ordinary meaning	"less than X%, and greater than or equal to the inherent lower limit enabled by the specification"

Just like the term "at least [X]%,<sup>7</sup>" the term "less than [X]%" has a plain and ordinary meaning. *See, e.g., In re Aldrich*, 398 F.2d 855, 863 (C.C.P.A. 1968) (describing "less than" as "clear words"); *Waddington N. Am., Inc. v. Sabert Corp.*, No. CIV.A. 09-4883 GEB, 2010 WL 4363137, at \*6 (D.N.J. Oct. 27, 2010) (" 'Less than' has a well known meaning to even a lay person . . ."). Proof positive of that plain and ordinary meaning: CSIRO recites "less than" in its own proposed construction of the term "at least [X]%" (*i.e.*, " . . . **less than** the inherent upper limit . . ."), as well as of the term "less than [X]%" (*i.e.*, " . . . **less than** X% . . ."). BASF respectfully submits that the compelling rationale for rejecting CSIRO's argument as to the term "at least [X]%" applies with equal force to the term "less than [X]%.<sup>7</sup>" There is no merit to unilaterally impose a floor of "greater than or equal to the inherent lower limit enabled by the specification" as proposed by CSIRO.

Claim 5 of the '226 Patent (dependent from claim 1 copied above in Section A) is representative of how the term "less than [X]%" is used in the claims at issue:

5. The process of claim 1, wherein the total fatty acid of the plant seed comprises at least 2.1% eicosapentaenoic acid and **less than 0.1% eicosatrienoic acid [*i.e.*, ETrA]** (w/w).

'226 Patent (D.I. 59-1), claim 5 (emphasis added). The plain language of the claim does not set a floor for the percentage of fatty acid. In relation to that requirement, the specification expressly

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<sup>7</sup> This claim term appears in the '849 Patent, claim 6; the '226 Patent, claim 5; the '572 Patent, claim 5; the '377 Patent, claim 5; the '432 Patent, claims 5, 28; the '410 Patent, claim 3; the '541 Patent, claims 1, 2, 15, 16; the '954 Patent, claims 1, 2, 15, 16; the '084 Patent, claims 1, 2, 4, 6, 10, 11.

discloses that there is no lower limit: “There are advantages to maximizing production of a desired LC-PUFA while minimizing the extent of side-reactions. In a particular embodiment, there is **little or no ETrA detected (less than 0.1%)** while the level of EPA is at least 2.1%.”<sup>8</sup> *Id.* at col.29 ll.41-44 (emphasis added). The intrinsic evidence is clear that “less than [X] %” is an open-ended range, without a lower limit, consistent with its plain and ordinary meaning.<sup>9</sup>

**C. The term “comprises [X] %” means “comprises exactly [X] %”;  
the “term “includes [X] %” means “includes exactly [X] %.”**

The terms “comprises [X] %” and “includes [X] %” specify a particular percentage of fatty acid produced in a claimed seed. BASF’s and CSIRO’s respective constructions are set forth in the table below.

<u>Term</u>	<u>BASF’s Proposed Construction</u>	<u>CSIRO’s Proposed Construction</u>
“comprises [X] %” <sup>10</sup>	“comprises exactly [X] %”	“greater than X%, and less than the inherent upper limit enabled by the specification”
“includes [X] %” <sup>11</sup>	“includes exactly [X] %”	“greater than X%, and less than the inherent upper limit enabled by the specification”

BASF’s proposed construction – that “[X] %,” without the term “at least” preceding it, means “exactly [X] %” – is supported by the plain language of the asserted claims. In contrast to

<sup>8</sup> This same disclosure appears in the ’849 Patent; the ’572 Patent; the ’377 Patent; the ’432 Patent; the ’410 Patent. And, there is no support in the remaining patent specifications for imposing a lower limit for the “less than [X] %” range.

<sup>9</sup> There is no disavowal of scope in the prosecution history with respect to this term.

<sup>10</sup> This claim term appears in the ’723 Patent, claims 1, 3-5, 18; the ’250 Patent, claims 4, 5; ’357 Patent, claims 25-27, 38, 42.

<sup>11</sup> This claim term appears in the ’250 Patent, claim 1.

other asserted claim terms with the words “at least” (*e.g.*, “comprises **at least** 2.5%”<sup>12</sup>), the terms “comprises [X] %” and “includes [X] %” conspicuously omit the words “at least.” The patentee’s decision to omit the open-ended “at least” language manifests its clear intent to restrict the claims to the exact percentage recited in the claims.

Claim 1 of the ’723 Patent is representative:

1. A process for producing eicosapentaenoic acid and docosapentaenoic acid, comprising the steps of (i) growing a transgenic oilseed plant which comprises eicosapentaenoic acid and docosapentaenoic acid in an esterified form as part of triglycerides in its seed and a microalgal fatty acid desaturase, wherein the total fatty acid of the seed **comprises 2.5%  $\omega$ 3 C20 fatty acids** (w/w) and wherein the docosapentaenoic acid is present at a level based on a **conversion ratio of eicosapentaenoic acid to docosapentaenoic acid of at least 5%** (w/w), and (ii) harvesting the seed from the transgenic plant.

’723 Patent (D.I. 60-3), claim 1 (emphasis added). Even within the above claim itself, the patentee used the words “at least” in the context of the recited conversion ratio, but specifically omitted those words when reciting the specific percentage (2.5%) of  $\omega$ 3 C20 fatty acids. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (“Because claim terms are normally used consistently throughout the patent, the usage of a term in one claim can often illuminate the meaning of the same term in other claims. Differences among claims can also be a useful guide in understanding the meaning of particular claim terms.”). CSIRO should be bound by its own distinction. Indeed, the originally-filed claim included the term “comprises **at least** 2.5% . . .,” and the patentee amended the claim to delete the “at least” language. Ex. 1 (’723 Patent File History, June 19, 2017 Amendment and Remarks) (“By this Amendment, applicant has amended claims 222 and 225-228 to remove the term ‘at least’ . . .”).<sup>13</sup>

<sup>12</sup> *See* Section A above.

<sup>13</sup> All references to “Ex.” herein refer to exhibits attached to the Declaration of Arlene L. Chow submitted herewith with BASF’s Opening Claim Construction Brief.

In the context of the claims at issue, the word “comprises” only indicates that the claimed seed can contain additional fatty acids, other than the claimed “ $\omega$ 3 C20 fatty acids.” That is the only way the specifications apply “comprises” or “includes” in relation to fatty acids, either broadly as a class (“ $\omega$ 3 C20 fatty acids”), or specifically (EPA and DPA):<sup>14</sup>

In a further embodiment, the cell **comprises  $\omega$ 3 polyunsaturated fatty acids** that are the products of  $\Delta$ 6-desaturation of ALA and/or the products of  $\Delta$ 9 elongation of ALA, and the efficiency of conversion of ALA to said products in the cell is at least 22% or at least 24%.

In yet another embodiment, the cell **comprises DPA**, and the total fatty acid of the cell comprises at least 0.1%, at least 0.13%, or at least 0.5% DPA.

In a further embodiment, the cell **comprises DPA**, and the efficiency of conversion of EPA to DPA in the cell is at least 5% or at least 7%.

In another embodiment, the cell **comprises EPA**, and wherein the total fatty acid of the cell comprises at least 1.5%, at least 2.1%, or at least 2.5% EPA.

In a further embodiment, the cell **comprises EPA**, and the efficiency of conversion of ALA to EPA in the cell is at least 2% or at least 14.6%.

’723 Patent (D.I. 60-3), col.31 ll.27-43 (emphasis added). When the patentee used “comprises,” it was allowing for other types of fatty acids; when the patentee used “at least,” it was defining a floor. As the Federal Circuit has noted, the words “comprises” and “includes” in the disputed claim terms only “raise[] a presumption that the **list of elements** is nonexclusive.” *Dippin’ Dots, Inc. v. Mosey*, 476 F.3d 1337, 1343 (Fed. Cir. 2007) (emphasis added). CSIRO should not be permitted to circumvent the Federal Circuit’s dictate that “comprises” and “includes” cannot be treated as “weasel word[s] with which to abrogate claim limitations.” *Id.*

CSIRO also argues for the same construction that it proposes for the term “at least [X]%,” *i.e.*, “greater than X%, and **less than the inherent upper limit enabled by the**

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<sup>14</sup> CSIRO agrees that “includes” and “comprises” have the same meaning. *See Lucent Techs., Inc. v. Gateway, Inc.*, 525 F.3d 1200, 1214 (Fed. Cir. 2008) (The Federal Circuit has “consistently interpreted ‘including’ and ‘comprising’ to have the same meaning.”).

**specification.**” BASF respectfully submits that the Court should reject CSIRO’s attempt to unilaterally impose a ceiling with an “inherent upper limit enabled by the specification,” for the same reasons discussed above in Section A, relating to the term “at least [X]%.”

**D. The term “SEQ ID NO:[X]” means  
“the exact sequence identified as SEQ ID NO:[X].”**

The term “SEQ ID NO:[X]” specifies a single DNA sequence that is disclosed in the specification, and is labeled by “SEQ ID NO:[X]” (or without the colon, *i.e.*, “SEQ ID NO [X]”). BASF’s and CSIRO’s respective constructions are set forth in the table below.

<u>Term</u>	<u>BASF’s Proposed Construction</u>	<u>CSIRO’s Proposed Construction</u>
“SEQ ID NO:[X]” <sup>15</sup>	“the exact sequence identified as SEQ ID NO:X”	no construction necessary  If construed, “the nucleotide or amino acid sequence identified by the number X in the relevant patent or an equivalent sequence.”

The term “SEQ ID NO:[X]” refers to the exact corresponding sequence disclosed in the specification. BASF’s construction is supported by the plain meaning of the term. *See Phillips*, 415 F.3d at 1314. There is no support for CSIRO’s alternative proposed construction that the term extends to “an equivalent sequence.” It is entirely unclear what sequences would be “equivalent.” Indeed, the term “equivalent sequence” is not present in the specification, prosecution history or claims. That alternative proposed construction also improperly drives CSIRO’s primary argument that no construction is necessary; CSIRO likely intends to argue to the jury that a non-identical sequence can somehow fall within the literal scope of the specific claim term “SEQ ID NO:[X].”

<sup>15</sup> This claim term appears in the ’579 Patent, claims 1, 7; the ’033 Patent, claims 1, 6, 15; the ’792 Patent, claims 1, 2; the ’880 Patent, claims 11, 20; the ’346 Patent, claims 1, 3, 5-7.

Claim 7 of the '579 Patent is representative of the usage of the term "SEQ ID NO:[X]" in the '579, '033, '880, and '792 Patents:

7. A Brassica plant cell comprising a polynucleotide which encodes a  $\Delta 5$  elongase operably linked to a promoter which directs expression of the polynucleotide in the plant cell; a polynucleotide which encodes a  $\Delta 6$  elongase which has the amino acid sequence set forth as **SEQ ID NO:31**, operably linked to a promoter which directs expression of the polynucleotide in the plant cell; a polynucleotide which encodes a  $\Delta 4$  desaturase whose amino acid sequence is **at least 99.5% identical to the sequence set forth as SEQ ID NO:33**, operably linked to a promoter which directs expression of the polynucleotide in the plant cell; a polynucleotide which encodes a  $\Delta 5$  desaturase which has the amino acid sequence set forth as **SEQ ID NO:18**, operably linked to a promoter which directs expression of the polynucleotide in the plant cell; a polynucleotide which encodes a  $\Delta 6$  desaturase operably linked to a promoter which directs expression of the polynucleotide in the plant cell; and an exogenous desaturase which desaturates an acyl-CoA substrate.

'579 Patent (D.I. 61-2), claim 7 (emphasis added). Consistent with BASF's proposed construction, the patentee only recited "SEQ ID NO:[X]" in relation to the specific sequence; when the patentee wished to depart from that specific sequence, it recited "at least [X]% identical to."<sup>16</sup> Claim 6 of the '346 Patent recites a "SEQ ID NO:[X]" without any reference to "at least [X]% identical to":

6. An isolated nucleic acid molecule comprising: (a) the nucleic acid sequence as shown in FIG. 3 (**SEQ ID NO: 6**) from nucleotides 1 to 398 wherein; or (b) a nucleic acid sequence that is complementary to the nucleic acid sequence of (a).

'346 Patent (D.I. 62-4), claim 6 (emphasis added).

In the specification, the patentee relied on other language to refer to sequences that are not 100% identical to a specific SEQ ID NO. For example, the '346 Patent defines the term "sequence that has substantial sequence **homology**" as ". . . includ[ing] nucleic acid sequences having at least 65%, more preferably at least 85%, and most preferably 90-95% identity with the

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<sup>16</sup> The corresponding specifications expressly disclose that "minimum % identity figures" are provided "where applicable." See '033 Patent (D.I. 62-1), col.37 ll.18-20; '792 Patent (D.I. 62-2), col.43 ll.32-34; '880 Patent (D.I. 62-3), col.33 ll.31-33.

nucleic acid sequences as shown in FIG. 1 (SEQ.ID.NO.:1), FIG. 2 (SEQ.ID.NO.:4), FIG. 3 (SEQ.ID.NO.:6) or FIG. 4 (SEQ.ID.NO.:8).” *Id.* at col.7 ll.20-32 (emphasis added). Similarly, the ’346 Patent defines the term “a nucleic acid sequence which is an analog” as “a nucleic acid sequence which has been **modified** as compared to the sequence of (a), (b) or (c) . . .” *Id.* at col.8 ll.20-22 (emphasis added).

During prosecution of the ’346 Patent, the patentee clearly and unambiguously disavowed any claim scope covering a homolog, analog or other non-identical version of the claimed sequences. The originally-prosecuted claim recited broadening language, such as “substantial sequence homology” and “an analog of.” But, that language was removed, because the Examiner found that the specification did not support inclusion of other sequences in the claims. *See, e.g.*, Ex. 2 (’346 Patent File History, May 1, 2007 Office Action) at 5-7; Ex. 3 (’346 Patent File History, January 17, 2008 Office Action) at 4-8; Ex. 4 (’346 Patent File History, December 16, 2008 Office Action) at 5. Ultimately, the claims of the ’346 Patent issued without the original broadening language, reciting instead the specific “SEQ ID NO:[X].” Given this disavowal by the patentee, the term should be restricted to that exact sequence.

**E. The term “seed-preferred promoter” is indefinite.**

The term “seed-preferred promoter” appears in claim 7 of the ’346 Patent (as well as in numerous unasserted claims of the ’346 Patent). BASF’s and CSIRO’s respective constructions are set forth in the table below.

<u>Term</u>	<u>BASF's Proposed Construction</u>	<u>CSIRO's Proposed Construction</u>
"seed-preferred promoter"	Indefinite	Non-limiting. If limiting, no construction necessary. If construed, "seed-specific promoter"

Claim 7 of the '346 Patent recites:

7. A chimeric nucleic acid molecule comprising: (a) a **seed-preferred promoter** obtained from flax which comprises: the nucleic acid sequence as shown in FIG. 3 (SEQ ID NO: 6) from nucleotides 1 to 398 and (b) a second nucleic acid sequence non-native to said flax **seed-preferred promoter**.

'346 Patent (D.I. 62-4), claim 7 (emphasis added).

The term "seed-preferred promoter" is indefinite. A person skilled in the art would not be able to ascertain with reasonable certainty the bounds of what constitutes a "seed-**preferred** promoter," as opposed to a "seed-**specific** promoter" (which is separately recited in the claims of the same patent). *See Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014) ("[A] patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention."). Notably, the patent specification provides no definition for "seed-preferred promoter." It appears only in the claims of the '346 Patent; the specification makes no mention of the term, either on its own or in relation to the separate and distinct term "seed-**specific** promoter."<sup>17</sup>

<sup>17</sup> In sharp contrast, the specification provides an express definition for the distinct term "seed-**specific** promoter," *i.e.*, "a gene expressed under the control of the promoter is predominantly expressed in plant seeds with no or no substantial expression, typically less than 5% of the overall expression level, in other plant tissues." '346 Patent (D.I. 62-4), col.5 ll. 18-22.



The Examiner coined the term “seed-preferred promoter” during prosecution of the ’346 Patent. In particular, the Examiner rejected the pending claims – which, at the time, were broadly directed to a genus of “seed-specific promoters” – as anticipated and obvious over Jain *et al.*, WO98/18948 (“Jain”). Ex. 2 (’346 Patent File History, May 1, 2007 Office Action) at 10. The Examiner explained that “Jain discloses two seed-preferred promoter sequences.” *Id.* But, the Examiner did not provide a particular definition for “seed-preferred promoter,” and did not indicate how it should be distinguished from the separate and distinct term “seed-specific promoter” that was already recited in the pending claims. As for Jain, it does not use the term “seed-preferred promoter”; nor does it suggest a definition for that term. The patentee argued in response that Jain discloses something different than a “seed-specific promoter” – without elaborating what “seed-preferred promoter” means. Ex. 5 (’346 Patent File History, October 31, 2007 Amendment and Reply) at 18 (“Jain does not teach the seed-specific promoters of the present invention.”). At one point, the Examiner also rejected the pending claims for lack of support in the specification, again distinguishing a “seed-preferred promoter” from a “seed-specific promoter,” without further elaboration:

[T]he specification, while being enabling for a method of using an isolated nucleic acid molecule comprising a nucleic acid sequence comprising bases 1-417 of SEQ ID NO: 6 having **seed-preferred promoter** activity and a transgenic plant transformed herewith, **does not reasonably provide enablement for a genus of seed-specific promoters** obtained from flax comprising an RY repeat and an ABRE promoter element . . .

Ex. 3 (’346 Patent File History, January 17, 2008 Office Action) at 7 (emphasis added). Thus, contrary to CSIRO’s position that “seed-specific promoter” and “seed-preferred promoter” should be treated synonymously, the patentee itself treated those two terms as distinct.

This Court has found a claim term to be indefinite on similar facts. *See Spherix Inc. v. Verizon Servs Corp.*, 119 F. Supp. 3d 453, 456-57 (E.D. Va. 2015). In *Spherix*, the Court

granted summary judgment of invalidity for indefiniteness, because “nothing in the specification explains an ‘interface for connecting’ or distinguishes it from the third element, an ‘interface module.’ ” *Id.* Likewise here, there is nothing in the specification (or anywhere else, such as the claim or prosecution history) that establishes the scope of a “seed-preferred promoter.”

To avoid a finding of indefiniteness, CSIRO argues that the term “seed-preferred promoter” is non-limiting. That argument lacks merit. Although there is no mention whatsoever in the specification of a “seed-preferred promoter,” the specification does emphasize the degree of promoter activity in a seed as an integral part of the alleged invention. For example, the title of the patent is “Flax **seed specific promoters**.” The Summary of the Invention states:

The present invention relates to improved methods for the **seed-specific expression** of non-native genes in plants. In particular, the invention relates to improved methods for the **seed-specific expression** of non-native genes in flax.

’346 Patent (D.I. 62-4), col.2 ll.64-67 (emphasis added). Still further, the Detailed Description of the Invention discloses: “The present invention provides novel flax **seed specific promoters** useful for the expression of non-native genes in flax seeds and the seeds of other plant species.”

*Id.* at col.5 ll.13-15 (emphasis added). And, during prosecution, the patentee repeatedly relied on alleged seed-specific activity of the claimed SEQ ID NO: 6 in order to distinguish over the prior art, before amending the claims to recite the disputed “seed-preferred promoter.” *See* Ex. 5 (’346 Patent File History, October 31, 2007 Amendment and Reply) at 17-18. Federal Circuit precedent is clear that, given the specification and prosecution history, the claim term is limiting. *See, e.g., Rotatable Techs. LLC v. Motorola Mobility LLC*, 567 F. App’x 941, 943 (Fed. Cir. 2014) (“The specification is replete with references to ‘selectively rotating,’ underscoring the importance of the feature to the claimed invention. . . . Further the prosecution history shows ‘clear reliance on the preamble’ to distinguish the claimed invention from the prior art”) (internal citations omitted); *Saffran v. Johnson & Johnson*, 712 F.3d 549, 559 (Fed. Cir. 2013) (“We

conclude that Saffran’s statements during prosecution of the ’760 patent limit ‘device’ to a continuous sheet. On multiple occasions during prosecution, Saffran sought to distinguish prior art by representing to the examiner that ‘[t]he device used is a sheet rather than a pre formed chamber (Gaskill).’”); *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1347 (Fed. Cir. 2002) (“[B]oth the specification and prosecution history indicate that the phrase ‘rich in glucosinolates’ helps to define the claimed invention and is, therefore, a limitation of claim 1”).

**F. The term “capable of directing expression . . . in [the cell/seed]” means “capable of causing expression . . . in [the cell/seed].”**

BASF’s and CSIRO’s respective constructions for the term “capable of directing expression . . . in [the cell/seed]” are set forth in the table below.

<u>Term</u>	<u>BASF’s Proposed Construction</u>	<u>CSIRO’s Proposed Construction</u>
“operably linked to one or more promoters that are capable of directing expression . . . in [the cell/seed]” <sup>18</sup>	The term “capable of directing expression . . . in [the cell/seed]” means “capable of causing expression . . . in [the cell/seed].”	No construction necessary. If construed, “linked to one or more promoters that are capable of stimulating or modulating the transcription of the coding sequence in an appropriate cell.”

Claim 1 of the ’357 Patent is representative of the claims at issue:

1. A recombinant plant cell which synthesises eicosapentaenoic acid (EPA), comprising more than one heterologous polynucleotide, wherein said polynucleotides encode: a) a  $\Delta 6$  desaturase, a  $\Delta 6$  elongase and a  $\Delta 5$  desaturase; or b) a  $\Delta 5/\Delta 6$  bifunctional desaturase and a  $\Delta 5/\Delta 6$  bifunctional elongase; wherein the more than one polynucleotides are **operably linked to one or more promoters that are capable of directing expression of said polynucleotides in the cell**, wherein the enzymes encoded by said polynucleotides comprise at least one desaturase which is able to act on an acyl-CoA substrate, and wherein the synthesis of EPA requires the sequential action of said enzymes.

<sup>18</sup> This claim term appears in the ’250 Patent, claims 8, 9; the ’357 Patent, claims 1, 8, 38-45.

'357 Patent (D.I. 61-3), claim 1 (emphasis added). BASF's proposed construction tracks the language of the claim, but clarifies that the phrase "directing expression" means "causing expression" in the particular cell/seed. BASF's construction is guided by the specific usage of the term "direct gene expression" in the specification, *i.e.*, that the expression vectors of the alleged invention "function (*i.e.*, direct gene expression)" in particular cells:

Expression vectors of the present invention include any vectors that **function (*i.e.*, direct gene expression)** in recombinant cells of the present invention, including in bacterial, fungal, endoparasite, arthropod, other animal, and plant cells. Preferred expression vectors of the present invention can **direct gene expression** in yeast, animal or plant cells.

*Id.* at col.39 ll.14-20 (emphasis added). Similarly, the specification discloses that constitutive promoters, *i.e.*, promoters that function continuously in all cell types, "direct continuous gene expression":

Constitutive promoters direct continuous gene expression in all cells types and at all times (e.g., actin, ubiquitin, CaMV 35S).

*Id.* at col.41 ll.60-62. That is "causing expression."

CSIRO's proposed construction is unduly broad. It reads out "expression," requiring instead "stimulating or modulating the **transcription** of the coding sequence." But transcription is a distinct step prior to expression. There is no basis in the claims or the specification for extending the term to transcription activity. Although CSIRO does not appear to dispute the general intent of the word "directing," it further broadens the term to cover "stimulating or modulating." And yet, stimulating expression does not necessarily mean there is expression. As for modulating, it can mean increasing or **decreasing**; the specification nowhere envisions promoters that decrease gene expression. "[T]he construction that stays true to the claim language and most naturally aligns with the patent's description of the invention, will be, in the

end, the correct construction.” *Renishaw PLC v. Marposs Societa’ per Azioni*, 158 F.3d 1243, 1249-50 (Fed. Cir. 1998). That is BASF’s proposed construction.

**G. The words “capable of” should not be read into the terms “catalyses [desaturation/elongation]” and “a desaturase [an exogenous desaturase] which desaturates an acyl-CoA substrate.”**

BASF’s and CSIRO’s respective constructions of the term “catalyses [desaturation/elongation]” and “a desaturase [an exogenous desaturase] which desaturates an acyl-CoA substrate” are set forth in the table below.

<u>Term</u>	<u>BASF’s Proposed Construction</u>	<u>CSIRO’s Proposed Construction</u>
“catalyses [desaturation/elongation]” <sup>19</sup>	The term “catalyses [desaturation/elongation]” means “[desaturates/elongates].”	No construction necessary. If construed, “a [desaturase/elongase] capable of catalyzing [desaturation/elongation] of [fatty acid 1] to [fatty acid 2].”
“a desaturase [an exogenous desaturase] which desaturates an acyl-CoA substrate” <sup>20</sup>	No construction necessary	No construction necessary. If construed, “a desaturase capable of desaturating an acyl-CoA substrate.”

Claim 1 of the ’880 Patent is representative of the claims at issue that recite the term “catalyses [desaturation/elongation]”:

1. A recombinant nucleic acid molecule comprising a polynucleotide which encodes a  $\Delta 5/\Delta 6$  bifunctional desaturase which **catalyses desaturation** of  $\alpha$ -linolenic acid (ALA) to stearidonic acid (SDA) and desaturation of eicosatetraenoic acid (ETA) to eicosapentaenoic acid (EPA); and a polynucleotide which encodes a  $\Delta 6$  elongase which **catalyses elongation** of SDA to ETA; wherein each polynucleotide is operably linked to a promoter which directs expression of the polynucleotide in a plant seed.

<sup>19</sup> This claim term appears in the ’880 Patent, claims 1, 2, 8, 9, 20.

<sup>20</sup> This claim term appears in the ’250 Patent, claims 1, 6, 7; the ’579 Patent, claims 1, 7; the ’033 Patent, claims 4, 5, 10, 19, 31, 32, 33, 34.

'880 Patent (D.I. 62-3), claim 1 (emphasis added).

The specification is clear that the term “catalyses [desaturation/elongation]” refers to the activity of desaturase and elongase enzymes, respectively, on their substrates. The claim term does not extend to enzymes that are merely “capable of” desaturating/elongating – as CSIRO proposes – if those enzymes do not perform that function in the seed at issue. For example, in describing the fatty acid synthesis pathway, the specification discloses that desaturases “catalyse[]” desaturation by “add[ing] an additional double bond into the fatty acid carbon chain”:

In one pathway (FIG. 1, II), the **desaturation reactions are catalysed by Δ6, Δ5, and Δ4 desaturases**, each of which **adds an additional double bond into the fatty acid carbon chain**, while each of a Δ6 and Δ5 elongase reaction adds a two-carbon unit to lengthen the chain.

*Id.* at col.2 ll.41-45 (emphasis added). Similarly, elongases “add[] a two-carbon unit to lengthen the chain.” *Id.* at col.2 ll.44-45.

CSIRO consistently reads in the phrase “capable of.” But that construction is contradicted by the specification, which draws a distinction between enzymes that “catalyse [desaturation/elongation]” and those that are capable or “**able to** catalyse [desaturation/elongation].” *Compare, e.g., id.* at col.3 ll.25-27 (“The enzyme Δ5 desaturase **catalyses** the further desaturation of C20 LC-PUFA leading to arachidonic acid (ARA, 20:4ω6) and EPA (20:5ω3).”) (emphasis added) and *id.* at col.25 ll.57-61 (“In one embodiment, the Δ5/Δ6 bifunctional elongase is **able to catalyse** the elongation of EPA to form DPA in a plant cell such as, for example, a higher plant cell, when that cell is provided with a source of EPA.”) (emphasis added).

BASF also opposes CSIRO’s attempt to read the words “capable of” into the term “a desaturase [an exogenous desaturase] which desaturates an acyl-CoA substrate.” The plain

language of the term requires a desaturase “which desaturates.” There is no basis for broadening that term beyond its plain language to extend the claimed desaturase to one which need only be “capable of” desaturating an acyl-CoA substrate. As discussed above, the specifications of the relevant patents distinguish between enzymes that “catalyse [desaturation/elongation]” and those that are “able to catalyse [desaturation/elongation].” The specifications emphasize that the disclosed enzymes are “at least capable of” desaturating and elongating, indicating that omission of the term “capable of” in the disputed terms was deliberate and intended to require more than the mere ability to desaturate/elongate. *See, e.g.*, ’849 Patent (D.I. 58-4), col.23 ll.16-20.

**H. The term “the extracted canola oil” does not require construction.**

<u>Term</u>	<u>BASF’s Proposed Construction</u>	<u>CSIRO’s Proposed Construction</u>
“the extracted canola oil” <sup>21</sup>	No construction necessary	“the extracted oil”

BASF respectfully submits that the term “the extracted canola oil” does not require construction. CSIRO’s construction follows the exact language of the claim term, but inexplicably drops the limitation “canola” from the term.

**I. Agreed-upon Constructions**

The parties agree that the following claim terms should have the following constructions:

<u>Term</u>	<u>Agreed-upon Construction</u>
“C20” / “C20 fatty acids” <sup>22</sup>	exactly 20 carbon atoms / fatty acids with exactly 20 carbon atoms

<sup>21</sup> This claim term appears in the ’541 Patent, claims 5, 18.

<sup>22</sup> This claim term appears in the ’849 Patent, claims 1, 3; the ’226 Patent, claims 1, 3, 9, 10; the ’572 Patent, claims 1, 3, 9, 10; the ’377 Patent, claims 1, 3, 9, 10; the ’432 Patent, claims 1, 3, 9, 10, 26, 31, 32; the ’410 Patent, claims 1, 6, 7; the ’723 Patent, claims 1, 4, 5, 18; the ’250 Patent, claims 1, 10; the ’357 Patent, claims 27, 38, 42; ’084 Patent, claims 2, 10.

<u>Term</u>	<u>Agreed-upon Construction</u>
“w/w” <sup>23</sup>	“weight percentage” or “weight by weight”
“conversion ratio” / “efficiency of conversion” <sup>24</sup>	“the amount of the LC-PUFA formed as a percentage of one or more substrate PUFA or LC-PUFA”
“claim 6” <sup>25</sup>	<p>“claim 6” in claim 15 of the ’346 Patent refers to claim 6 of the ’346 Patent</p> <p>“claim 6” in claim 16 of the ’346 Patent refers to claim 7 of the ’346 Patent</p>
“about” <sup>26</sup>	<p>The term “about” means “+/-10% of the recited value.”</p> <p>Thus, e.g., the term “about 30%” means “27- 33%” and not “20-40%.”</p>
“new ω6 [polyunsaturated] fatty acids” / “new ω3 [polyunsaturated] fatty acids” <sup>27</sup>	<p>“new ω6 [polyunsaturated] fatty acids” means “the sum of all the ω6 fatty acids excluding LA.” The parties explicitly note that the category ‘ω6 fatty acids’ excludes ω3 fatty acids and monounsaturated fatty acids.</p> <p>“new ω3 [polyunsaturated] fatty acids” means “the sum of all the ω3 fatty acids excluding ALA.” The parties explicitly note that the category ‘ω3 fatty acids’ excludes ω6 fatty acids and monounsaturated fatty acids.</p>

<sup>23</sup> This claim term appears in the ’849 Patent, claims 1, 3-6, 10; the ’226 Patent, claims 1, 3-7, 9-18; the ’572 Patent, claims 1, 3-7, 9-18; the ’377 Patent, claims 1, 3-7, 9-18; the ’432 Patent, claims 1, 3-7, 9-18, 26-29, 31-40; the ’410 Patent, claims 1-4, 6-15; the ’723 Patent, claims 1, 2, 4-10, 16, 18; the ’250 Patent, claims 1, 4, 5.

<sup>24</sup> This claim term appears in the ’226 Patent, claims 1, 13, 16; the ’572 Patent, claims 1, 13, 16; the ’377 Patent, claims 1, 13, 16; the ’432 Patent, claims 1, 13, 16, 26, 35, 38; the ’410 Patent, claims 1, 10, 13; the ’723 Patent, claims 1, 7, 9, 16; the ’357 Patent, claims 28-30, 39-41, 43-45.

<sup>25</sup> This claim term appears in the ’346 Patent, claims 15, 16.

<sup>26</sup> This claim term appears in the ’541 Patent, claims 10-13, 15, 23-26; the ’954 Patent, claims 10-13, 15, 23-26; the ’084 Patent claim 2.

<sup>27</sup> This claim term appears in the ’541 Patent, claims 5, 18; the ’954 Patent, claims 5, 18; the ’084 Patent, claims 2, 8.



<u>Term</u>	Agreed-upon Construction
“A Brassica plant cell for producing [DPA] and [DHA] in an esterified form as part of triacylglycerols in the plant cell” / “in an esterified form as part of triglycerides” <sup>28</sup>	No construction necessary. The parties agree that the terms “triacylglycerols” and “triglycerides” have identical meanings.

## V. CONCLUSION

For the reasons set forth above, BASF respectfully requests that the Court adopt BASF’s proposed claim constructions as set forth herein.

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Respectfully submitted,

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<sup>28</sup> This claim term appears in the ’572 Patent, claim 1; the ’377 Patent, claim 1; the ’432 Patent, claims 1, 26; the ’410 Patent, claim 1; the ’723 Patent, claim 1, 16, 18, 20; the ’250 Patent, claim 1; the ’579 Patent, claim 1, 5, 12, 13; the ’033 Patent, claims 1, 9, 18, 24, 25, 27-30; the ’792 Patent, claim 10; the ’541 Patent claims 1, 15; the ’954 Patent, claim 7; the ’084 Patent, claim 1.

**CERTIFICATE OF SERVICE**

I hereby certify that a true copy of the foregoing BASF PLANT SCIENCE, LP'S AND BASF PLANT SCIENCE GMBH'S OPENING CLAIM CONSTRUCTION BRIEF was caused to be served on February 27, 2019 via email and/or the CM/ECF system upon all counsel of record.

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